

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

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OCT 22 2003

FILED BY: *Chencher*
Deputy Clerk

UNIMED PHARMACEUTICALS,
INC.,
a Delaware Corporation, and
LABORATORIES BESINS
ISCOVESCO,
a Delaware Corporation

Plaintiffs,

v.

PADDOCK LABORATORIES, INC.,
a Minnesota Corporation,

Defendant.

Civil Action
File No. 1:03-CV-2503

TWT

ANSWER AND COUNTERCLAIM

Defendant Paddock Laboratories, Inc. ("Paddock") answers the First Amended Complaint of Plaintiffs Unimed Pharmaceuticals, Inc. ("Unimed") and Laboratories Besins Iscovesco ("Besins") (collectively, "Plaintiffs") as follows:

THE PARTIES

1. Paddock lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 1.
2. Paddock lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 2.

3. Paddock lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 3.

4. Paddock denies the allegations contained in paragraph 4, except admits that it is incorporated under the laws of the State of Minnesota and its principal place of business is located at 3940 Quebec Ave. No., Minneapolis, Minnesota.

JURISDICTION

5. The allegations of paragraph 6 are conclusions of law to which no response is required. To the extent that a response is required, Paddock admits that the Complaint purports to state a cause of action for patent infringement as set forth in paragraph 5 and that the Court has subject matter jurisdiction, and otherwise denies the allegations.

6. The allegations contained in paragraph 6 are conclusions of law to which no response is required. To the extent a response is required, Paddock does not contest personal jurisdiction in this Court for purposes of this action and otherwise denies the allegations.

VENUE

7. The allegations contained in paragraph 7 are conclusions of law to which no response is required. To the extent a response is required, Paddock does

not contest venue in this district for purposes of this Action and otherwise denies the allegations.

COUNT 1

8. Paddock incorporates by reference its responses to Paragraphs 1 through 7 as if fully set forth herein.

9. Paddock denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 9, except admits that the allegations of paragraph 9 as to ownership of the '894 Patent are consistent with the assignee information on the face of the patent-in-suit and admits that what appears to be an accurate copy of the '894 Patent is attached as Exhibit 1 to the Complaint.

10. Paddock admits, on information and belief, that Unimed is the holder of a New Drug Application ("NDA") for the product Androgel®, and admits that the '894 Patent is listed in the FDA's "Orange Book", and otherwise denies the allegations of paragraph 10.

11. Paddock denies the allegations contained in paragraph 11, except admits that it has submitted an Abbreviated New Drug Application (the "ANDA") to the FDA with respect to a testosterone 1% topical gel product and respectfully refers to that ANDA for its contents.

12. Paddock admits the allegations contained in paragraph 12.

13. Paddock denies the allegations contained in paragraph 13.

14. Paddock admits the allegations contained in paragraph 14.

15. Paddock denies the allegations contained in paragraph 15.

16. Paddock denies the allegations contained in paragraph 16.

17. The allegations of paragraph 17 are conclusions of law to which no response is required. To the extent a response is required, Paddock denies the allegations, except refers to 35 U.S.C. §282 for its contents.

18. Paddock denies the allegations contained in paragraph 18 insofar as they allege that Paddock has engaged in infringing acts and denies knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations.

19. Paddock admits the allegations contained in paragraph 19.

20. The allegations of paragraph 20 are conclusions of law to which no response is required. To the extent a response is required, those allegations are denied.

21. The allegations of paragraph 21 are conclusions of law to which no response is required. To the extent a response is required, those allegations are denied.

22. Paddock denies the allegations contained in paragraph 22.

23. Paddock denies the allegations contained in paragraph 23.

24. Paddock denies the allegations contained in paragraph 24.

25. The allegations contained in paragraph 25 are conclusions of law to which no response is required, except Paddock admits that this Action was filed within 45 days of Plaintiffs' receipt of the notice of the ANDA filing.

AFFIRMATIVE DEFENSES

First Affirmative Defense

26. Paddock's product does not and will not infringe the claims of the patent-in-suit.

Second Affirmative Defense

27. One or more claims of the patent-in-suit are invalid under Title 35 of the United States Code.

COUNTERCLAIM

Defendant/Counterclaimant Paddock Laboratories, Inc. ("Paddock") brings the following Counterclaim against Plaintiffs/Counterdefendants Unimed Pharmaceuticals, Inc. ("Unimed") and Laboratories Besins Iscovesco ("Besins") (collectively, "Counterdefendants").

JURISDICTION AND VENUE

1. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States.

2. The Court has jurisdiction over this counterclaim pursuant to 28 U.S.C. § 1331 and § 1338(a); and Counterdefendants have expressly invoked the jurisdiction of this Court.

3. Venue properly exists in this judicial district pursuant to 28 U.S.C. § 1391, and by Counterdefendants' choice of forum.

THE PARTIES

4. Paddock is a corporation organized under the laws of the State of Minnesota and has its principal place of business at 3940 Quebec Ave. No., Minneapolis, Minnesota.

5. Upon information and belief, counterdefendant Unimed is a corporation organized under the laws of the State of Delaware and has its principal place of business in Marietta, Georgia.

6. Upon information and belief, counterdefendant Besins is a corporation organized under the laws of the State of Delaware and has its principal place of business in Herndon, Virginia.

COUNTERCLAIM FOR DECLARATION OF NON-INFRINGEMENT AND/OR INVALIDITY OF THE '894 PATENT

7. Paddock incorporates by reference and realleges each of the allegations set forth in paragraphs 1 through 6 of this Counterclaim.

8. Counterdefendants have filed in this Court an infringement action to enforce U.S. Patent No. 6,503,894 (the "'894 patent") (the "patent-in-suit").

Paddock has denied that it has infringed or will infringe any claims of the patent-in-suit and has alleged that one or more of the claims of the patent-in-suit are invalid. An actual controversy therefore exists between the parties on the issues thus making declaratory relief both appropriate and necessary.

DEMAND FOR JUDGMENT

WHEREFORE, Paddock prays for relief as follows:

A. That all claims against Paddock be dismissed with prejudice in their entirety and that all relief requested by Plaintiffs/Counterdefendants be denied;

B. That a judgment be entered that Paddock's ANDA seeking approval to commercially manufacture, use, or sell its testosterone gel has not infringed and does not infringe any claims of the patent-in-suit, that Paddock has a lawful right to continue with its ANDA application for a testosterone gel, and that Paddock's commercial manufacture, use, sale or importation of its testosterone gel, once approved by the FDA, will not infringe the patent-in-suit;

C. That a judgment be entered declaring that one or more claims of the patent-in-suit are invalid, and thus unenforceable against Paddock, its officers, agents, servants, and employees;

D. That the Plaintiffs/Counterdefendants, their successors-in-interest, agents, representatives, and attorneys be permanently enjoined from asserting or otherwise seeking to enforce the patent-in-suit against Paddock, its successors-in-

interest, or any of its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers;

E. That a judgment be entered that this action is an exceptional case within the provision of 35 U.S.C. § 285 and that Paddock is therefore entitled to a recovery of its reasonable attorney fees upon prevailing in this action;

F. That Paddock be awarded costs, attorneys fees and other relief, both legal and equitable, to which it may be justly entitled; and

G. That Paddock be awarded such other and further relief as just and proper.

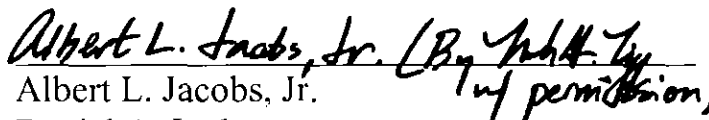
Respectfully submitted,



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Attorneys for Defendant/Counterclaimant
Paddock Laboratories, Inc.

Dated: October 22, 2003


CERTIFICATE OF SERVICE

This is to certify that I have this day served counsel of record in the foregoing matter with ANSWER AND COUNTERCLAIM OF PADDOCK LABORATORIES, INC. by depositing copies of same in the United States Mail in envelopes with sufficient postage thereon properly addressed as follows:

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This 22nd day of October, 2003.



Mark G. Tagg

Counsel for
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